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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,610	09/26/2001	Adam S. Cantor	56032US022	8132

32692 7590 06/04/2003

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EXAMINER	
JOYNES, ROBERT M	

ART UNIT	PAPER NUMBER
1615	8

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/965,610	Applicant(s) CANTOR ET AL.	
	Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-38* is/are pending in the application.

4a) Of the above claim(s) *22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 23-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on March 17, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-21 and 23-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garbe et al. (WO 96/08229) in view of Cleary (EP 0483105 A1). Garbe teaches a transdermal drug delivery device comprising a backing and a matrix comprising a copolymer, a softener and a drug (Page 2, lines 5-23). The copolymer comprises one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 10 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 10 carbon atoms in the alkyl group; one or more ethylenically unsaturated B monomers copolymerizable with the A monomers and a macromonomer

copolymerizable with the A and B monomers (Page 2, lines 5-23). The A monomers are taught on Page 4, lines 3-14. The B monomers are taught on Page 4, line 15 through Page 5, line 12. The macromonomers are taught on Page 5, line 13 through Page 8, line 28. Polymethylmethacrylate macromonomers are preferred (Page 6, lines 17-18). The macromonomer is generally present in an amount of not more than 30% by weight based on the total weight of all monomers in the copolymer (Page 5, lines 2-23).

The softeners of the delivery device include fatty acids, fatty alcohols, fatty acid esters as well as drugs that act as softeners (Page 8, line 29 – Page 10, line 15). Softeners can be included in amounts up to 60% by weight of the matrix (Page 10, lines 7-15).

Garbe further contemplates various drugs for delivery by the device including analgesics such as fentanyl (Page 12, line 7 – Page 13, line 20). The drug is present in the transdermal device in an amount of about 0.01 to about 30 percent by weight (Page 13, lines 16-18). Also, the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (Page 13, line 18-20).

Garbe does not expressly disclose the exact concentration ranges in the instant claims nor does it teach specifically that fentanyl in the drug delivered. Fentanyl is listed as a possible acceptable drug for transdermal delivery.

Cleary teaches a transdermal delivery device comprising fentanyl and absorption enhancers in a matrix (Page 10, Claims 1-7). The absorption enhancers are fatty acid esters or fatty alcohol ethers (Page 10, Claim 1).

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a transdermal delivery device wherein a copolymer matrix containing acrylate and methacrylate monomers and a macromonomer further contains fentanyl and enhancing adjuvants. Garbe teaches the delivery device and lists suitable drugs for delivery by the device. Cleary teaches that fentanyl is known to be delivery transdermally in the presence of absorption enhancing agents. It is obvious to place fentanyl in the delivery device of Garbe.

One of ordinary skill in the art would have been motivated to do this to provide a transdermal drug delivery device that allows dissolution of drug and relatively heavy loading with oily excipients, maintains contact with the skin and can be removed cleanly from the skin.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed March 17,2003 have been fully considered but they are not persuasive. Applicants argue that the prior art fails to suggest a transdermal

delivery system that contains about 8% to about 30% fentanyl wherein the composition is substantially free of undissolved fentanyl. Further, applicants argue that the prior art fails to teach a composition wherein the fentanyl is delivered over an extended period of time (about4 to about 14 days).

The Examiner finds these arguments unpersuasive. The prior art (Garbe) teaches a transdermal delivery system wherein the active agent to be delivery is present from about 0.01% to about 30%. This range completely encompasses the range recited in the instant claims. Further, the prior art teaches that fentanyl can be the active agent in the transdermal device. The secondary reference, Cleary, teaches that fentanyl is known to be delivered through transdermal devices. Still further the prior art states that the drug is substantially fully dissolved, and the matrix is substantially free of solid undissolved drug (Page 13, line 18-20). Therefore, the prior art does teach transdermal devices that contain fentanyl in amount of about 0.01% to about 30% wherein the composition is substantially free of solid undissolved drug. Any arguments to the contrary are not persuasive.

As for the time of delivery, the prior art teaches devices that contain fentanyl that are to be worn for 1 to 7 days (See Cleary, Page 6, lines 28-33). Therefore, the prior art teaches that the transdermal delivery system containing fentanyl is to be worn for a number of days.

It is the position of the Examiner that the prior art is suggestive of the device of the instant claims. Further, the Examiner fails to see the criticality in the recited concentration ranges for the fentanyl and the length of time the drug is to be delivered.

Absent a clear showing of the criticality, the determination of the particular concentrations or time of delivery is within the skill of the ordinary worker as part of the process of normal optimization.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
May 27, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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